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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,118	10/30/2001	Stanford Mark Moran	BMED-004/01US	8022

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EXAMINER	
SEHARASEYON, JEGATHEESAN	
ART UNIT	PAPER NUMBER
1647	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/26/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/004,118	MORAN, STANFORD MARK	
	Examiner	Art Unit	
	Jegatheesan Seharaseyon, Ph.D	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-17,19,20,24-27,29-33,35-38,40-47,49-54 and 68-88* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-17, 19, 20, 24-27, 29-33, 35-38, 40-47, 49-54 and 68-88* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is in response Applicants remarks and amendment filed 10/4/2005. Claims50-52 29 are amended. Thus, claims 2-17, 19, 20, 22, 24-27, 29-33, 35-38, 40-47, 49-54 and 68-88 are pending and under consideration in this action.

2. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103, maintained

3. The rejection of claims 2, 3, 8, 10, 14-17, 19, 22, 24, 30, 33, 35-38, 40-47, 49-54, 68-77 and 84-85 under 35 U.S.C. 103(a) as unpatentable over Sorenson in view of Palmeri and Harper is maintained for reasons of record in the Office Actions dated 18 March 2004, 15 December 2004, 28 September 2005 and 9 June 2006.

The instant invention is drawn to a method of treating an interferon-responsive disorder in a subject comprising determining a well-tolerated, therapeutic pharmacokinetic profile for interferon therapy in a subject by administration of one or more interferons formulated for short-term delivery to the subject and monitoring the subject for therapeutic and adverse effects; and administering to the subject using at least one internally presented, not externally programmable pump one or more interferons formulated for long-term delivery in which the interferons are released from the pump at a rate that substantially achieves the pharmacokinetic profile during long-term delivery.

Applicants' arguments filed 10/4/2006 have been fully considered but have not been found to be persuasive. It is also noted that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

As argued previously Applicants continue to argue that the cited art does not support the obviousness rejection. Applicants argue that Sorenson et al. provide a subject with an initial peak level of drug concentration that is followed by lower maintenance levels (see page 14 of the response filed 10/4/06). Thus, Applicant asserts that in Sorenson et al., the maintenance level cannot achieve the peak value because the maintenance level is reached by allowing the peak value to subside. Therefore, in at least this respect, Sorenson et al. teach away from the claimed invention in which the long-term formulation achieves the pharmacokinetic profile of the short-term formulation. Further, Applicant asserts that the Office has not taken issue with Applicant's interpretation of Sorenson et al. Applicant also argues that in view of the Office's statement that Sorenson et al. was included in the rejection for another purpose, it is asserted that the Office is not viewing Sorenson et al. as a whole and, in addition, is using impermissible hindsight analysis to formulate its rejection.

Applicant's arguments have been fully considered but are not found to be persuasive. Contrary to Applicant's assertion Sorenson et al. reference was considered as a whole and teachings relevant to the instant invention were recited in the previous Office Actions (15 December 2004, 28 September 2005 and 9 June 2006). Specifically,

Sorenson teaches a method of optimizing interferon doses in which a first level and then a second level is given to the subject as claimed in the instant invention. In addition, this teaching does not teach away from the instant invention. Thus, the Office does take issue with Applicant's assertion that the reference teaches away from the instant invention. In addition, any deficiency present in the Sorenson et al. (primary) reference is taught by Palmeri et al. and Harper et al.

Further, in response to Applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Applicant also assert that the Offices contention that the Palmeri et al. "was included to teach the administration of different levels of interferon to achieve an optimal dosage" is a mischaracterization of Palmeri et al. because Palmeri et al. describe a study to determine a maximally tolerated dose of recombinant alpha interferon in combination with 5-FU. While it is true that Palmeri et al. administered interferon-alpha in combination with 5-FU, the reference teaches the optimization of interferon-alpha to reduce the side effects (summary). Contrary to Applicant's assertion that Palmeri et al. do not suggest that the maximally tolerated dose is therapeutic or is in any way optimal,

the reference clearly teaches that the maximally tolerated dose of raIFN-2a is 9x 10^6 IU given subcutaneously three times/week (see page 330).

Contrary to Applicant's assertion that Palmeri et al. does not teach or suggest that long-term delivery of interferon is a problem in the treatment of colorectal cancer, one of skilled in the art recognizes that long-term delivery of interferon with out side effects is a problem in the treatment of colorectal cancer. In considering the disclosure of a reference, it is proper to take into account not only specific teaching of the reference but also the inferences which one skilled in the art would be reasonably be expected to draw therefrom *In re Preda*, 401 F.2d 825, 159 USPQ 342, 344 (CCPA 1968). Further, Applicants arguments that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, is not found to be persuasive for reasons set forth above.

Applicant also argues that the Harper et al. reference does not cure the deficiencies of Sorenson et al. or Palmeri et al. However as noted in the previous Office Actions of 18 March 2004, 15 December 2004, 28 September 2005 and 9 June 2006 Harper et al. was sited for teaching an implantable pump used for long-term administration of interferons.

Finally, Applicants assertion that references alone or in combination at least do not teach or suggest all claim limitations and therefore there can be no motivation to combine the references to arrive at the claimed invention. Applicant also asserts that that the Office has not viewed the references as a whole and has used impermissible hindsight analysis to combine the references to arrive at the claimed invention. These

arguments have been fully considered above and addressed. However, Sorenson teaches a method of optimizing interferon doses in which a first level and then a second level is given. Palmeri teaches a need for such optimization and Harper teaches a implantable pump that is useful for such optimized administration. The combination of Sorenson, Palmeri, and Harper suggests to the artisan of ordinary skill a method of treatment that optimizes interferon doses by administering a first level and then administering a second level, using an internal pump. Furthermore, the courts have held that:

Specific statements in the references themselves which would spell out the claimed invention are not necessary to show obviousness, since questions of obviousness involves not only what references expressly teach, but what they would collectively suggest to one of ordinary skill in the art. See CTS Corp. v. Electro Materials Corp. of America 202 USPQ 22 (DC SNY 1979); and In re Burckel 201 USPQ 67 (CCPA 1979).

and

In considering the disclosure of a reference, it is proper to take into account not only specific teaching of the reference but also the inferences which one skilled in the art would be reasonably be expected to draw therefrom In re Preda, 401 F.2d 825, 159 USPQ 342, 344 (CCPA 1968).

and

it is not necessary that the claimed invention be expressly suggested in any one or all of the references to justify combining their teachings; rather the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art *In re Keller,* 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Therefore rejections of record are maintained for reasons of record.

4. The rejection of claims 3-7, 12, 13, 19, 20, 22, 24-27, 29, 32, 33, 68, 74, 78-83 and 86-88 under 35 U.S.C. 103(a) as unpatentable over Sorenson in view of Palmeri

and Harper and further in view of Johnson is maintained for reasons of record in the Office Actions dated 18 March 2004, 15 December 2004, September 2005 and 9 June 2006.

Applicants' arguments with respect to Sorenson, Palmeri and Harper have been addressed above in paragraph 3. Applicants assert that Johnson et al. reference does not cure the deficiency of the Sorenson, Palmeri and Harper references. This is not found to be persuasive because Johnson reference was included to teach the various types of interferons and their use in the treatment of disease. Therefore as stated previously in the Office Actions dated 18 March 2004, 15 December 2004, 28 September 2005, and 9 June 2006 and above, the rejections of record are maintained.

5. The rejection of claims 2, 11, 22, 31, 68 and 74 under 35 U.S.C. 103(a) as unpatentable over Sorenson in view of Palmeri, Harper, and Johnson and further in view of Kwan is maintained for reasons of record in the office action of 18 March 2004, 15 December 2004, 28 September 2005 and 9 June 2006.

Applicants' arguments with respect to Sorenson, Palmeri, Harper and Johnson have been addressed above in paragraphs 3 and 4. Applicants assert that Kwan et al. reference does not cure the deficiency of the Sorenson, Palmeri, Harper and Johnson references. This is not found to be persuasive because Kwan reference was included to teach a pharmaceutical composition of interferons that retards microbial growth for longer than four weeks and teaches the advantages of such compositions. Therefore as stated previously in the Office Actions dated 18 March 2004, 15 December 2004, 28 September 2005 and 9 June 2006 and above the rejections of record are maintained.

6.The rejection of claims 2-17, 19, 20, 22, 24-27, 29-33, 35-38, 40-47, 49-54 and 68-88 under 35 U.S.C. 103(a) as being unpatentable over Sorenson in view of Palmeri, Peery et al. (U. S. Patent No. 5, 728, 396), and Johnson and further in view of Kwan is maintained for reasons of record in the office action of 9 June 2006.

Applicants' arguments with respect to Sorenson, Palmeri, Harper, Johnson and Kwan have been addressed above in paragraphs 3, 4 and 5. Applicants assert that Peery et al. reference does not cure the deficiency of the Sorenson, Palmeri, Harper Johnson and Kwan references. This is not found to be persuasive because Peery reference was included to teach an osmotic pump that is implanted. It also discloses that this pump once implanted has no mechanism to change the infusion rate. Therefore as stated previously in the Office Actions dated 9 June 2006 and above the rejections of record are maintained.

Claim Rejections - 35 USC § 112, second paragraph, maintained

7. The rejection of Claim 68 for reciting the limitation "said pharmacokinetic profile during said long-term delivery" on line 9 as lacking sufficient antecedent basis for this limitation in the claim is maintained.

Conclusion

8. No claims are allowable.

9. **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon, Ph.D whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JS
Art Unit 1647
December 14, 2006

CHRISTINE J. SAOUD
PRIMARY EXAMINER
Christine J. Saoud